§ 1262.307 Decision.

(a) The adjudicative officer shall issue an initial decision on the application with 90 calendar days after completion of proceedings on the application. The decision shall include written findings and conclusions on such of the following as are relevant to the decision:

* * * * *

§ 1262.309 [Amended]

6. In section 1262.309, last sentence, the word ''amont'' is revised to read ''amount''.

Dated: March 3, 1995.

Daniel S. Goldin,

Administrator.

[FR Doc. 95–5669 Filed 3–7–95; 8:45 am]

BILLING CODE 7510–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket Nos. 89F–0011 and 93F–0384]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sources of radiation to irradiate frozen, packaged meats for use in the National Aeronautics and Space Administration (NASA) space flight programs. FDA is also amending the food additive regulations to permit the use of packaging materials that are not otherwise listed in the regulations regarding food irradiation in the irradiation of frozen, packaged meats for use in the NASA space flight programs. This action is in response to two petitions filed by NASA.

DATES: Effective March 8, 1995; written objections and requests for a hearing by April 7, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of February 6, 1989 (54 FR 5679), FDA announced that a food additive petition (FAP 9M4125) had been filed by NASA, Washington, DC 20546, proposing that the food additive regulations be amended to provide for the safe use of sources of radiation to process beefsteaks for use in space flight programs.

In a tentative final rule published in the **Federal Register** of December 8, 1993 (58 FR 64526), FDA announced its tentative decision to amend the food additive regulations to provide for the safe use of sources of radiation to irradiate frozen, packaged beefsteak for use in NASA's space flight programs. FDA also announced its tentative final decision to amend the food additive regulations to permit the use of packaging materials that are not listed in the regulations regarding food irradiation in the irradiation of frozen, packaged beefsteak for use in the NASA space flight programs. The agency published a tentative final rule before proceeding to final action because it was including provisions regarding the packaging materials to be used with the beefsteaks that it had not announced in the notice of filing for the petition (FAP 9M4125). Interested persons were given the opportunity to comment on FDA's tentative decision. FDA did not receive any comments in response to this tentative final rule.

In the meantime, in a notice published in the **Federal Register** of November 19, 1993 (58 FR 61093), FDA announced that a food additive petition (FAP 3M4394) had been filed by NASA, Lyndon B. Johnson Space Center, Houston, TX 77058, proposing that the food additive regulations be amended to provide for the safe use of sources of radiation to process certain prepackaged meats for use in NASA space flight programs and to permit the use of packaging materials that are not listed in the regulations regarding food irradiation in the irradiation of the meats for use in NASA space flight programs. Interested persons were given the opportunity to comment on the environmental assessment submitted in the petition. No comments were received.

The amendment to the food additive regulations proposed in FAP 9M4125 is encompassed by that proposed in FAP 3M4394. This rule is the agency's final decision with respect to both FAP 3M4394 and FAP 9M4125.

II. Evaluation of Safety

In assessing the safety of food additives, including the use of irradiation in the processing of food, the agency usually considers the effects of lifetime daily exposure to the additive. The requested use, however, is limited to NASA's space flight programs. The amount of irradiated meat that could be consumed by individuals in the programs would constitute an extremely small fraction of their diets when considered over a lifetime. Because of this factor, questions regarding acute hazards, including those resulting from pathogenic organisms that could be present in the food, are more significant in evaluating this petitioned use of a source of radiation than they would ordinarily be in deciding whether to list a food additive. The petitions have requested that FDA authorize the use of irradiation processing only under conditions that ensure the microbial sterility of the product and the integrity of the product packaging. NASA has stated that it will ensure these qualities of sterility and packaging integrity by requiring adherence to an irradiation processing protocol (scheduled process) that it submitted with both petitions (Ref. 1). NASA's protocol specifies a minimum dose of 44 kiloGrays (kGy) in order to ensure sterility of the treated meat (Ref. 1).

Having evaluated the data in the petitions and other relevant material in its files, the agency finds that radiation-sterilized meats will be at least as nutritious as those sterilized by conventional means. FDA also finds that the total amount of radiolytic products that are produced in the meats during irradiation processing, and that will be consumed by individuals in the space flight programs, will be too small to be of any toxicological significance. Likewise, FDA finds that the total amount of radiolytic products that could be formed in the packaging materials during irradiation processing, and then migrate to the food and subsequently be consumed by individuals in the space flight programs, is too small to be of any toxicological significance (Refs. 2 and 3).

Section 179.25(c) (21 CFR 179.25(c)) restricts packaging materials used in the irradiation of prepackaged foods to those materials listed in § 179.45 (21 CFR 179.45), namely, those that have been demonstrated to be safe for use during irradiation of prepackaged foods, assuming that those foods would be consumed daily over a lifetime. The agency finds that this restriction is unnecessary for packaging that is to be used only in space flight programs. The

final regulation set forth below, therefore, exempts this packaging from the requirement in § 179.25(c) that packaging materials be restricted to those listed in § 179.45, provided that FDA has listed the packaging as safe for holding food in the applicable regulations ((parts 174 through 186) (21 CFR parts 174 through 186)).

III. Conclusions

The agency finds that meats irradiated at a minimum dose of 44 kGy and handled in accordance with the provisions of § 179.25(d) will meet current standards for commercial sterility and nutritional adequacy. The protocol submitted by NASA (Ref. 1) in its petitions is a scheduled process that satisfies the requirements of § 179.25(d) because, among other things, it sets forth procedures that will ensure that the minimum dose will be delivered. The agency concludes, therefore, that the proposed use of sources of radiation is safe, and that § 179.26 of the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before April 7, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Army Natick RD & E Center, ''Space Food Prototype, Production Guide No. 60–C,'' April 13, 1993.

2. Memorandum from M. DiNovi, Chemistry Review Branch, CFSAN, FDA, to P. Hansen, Biotechnology Policy Branch, CFSAN, FDA, dated April 29, 1994.

3. Memorandum from H. Irausquin, Division of Health Effects Evaluation, CFSAN, FDA, to P. Hansen, Biotechnology Policy Branch, CFSAN, FDA, dated November 9, 1994.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: Secs. 201, 402, 403, 409, 703, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 373, 374).

2. Section 179.26 is amended in the table in paragraph (b) by adding a new entry ''7.'' under the headings ''Use'' and ''Limitations'' to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * *	* *
7. For the sterilization of frozen, packaged meats used solely in the National Aeronautics and Space Administration space flight programs.	Minimum dose 44 kGy (4.4 Mrad). Packaging materials used need not comply with § 179.25(c) provided that their use is otherwise permitted by applicable regulations in parts 174 through 186 of this chapter.

* * * * *

Dated: February 26, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–5672 Filed 3–7–95; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD–FRL–5165–3]

RIN 2060–AD97

National Emission Standards for Hazardous Air Pollutants Final Standards for Epoxy Resins Production and Non-Nylon Polyamides Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates final standards that limit emissions of hazardous air pollutants (HAP) from existing and new epoxy resins and non-nylon polyamides production operations that are located at major sources. The EPA is in the process of developing standards for a wide range of types of polymer and resin production facilities. The polymers and resins covered by this rule use epichlorohydrin as a feedstock. This rulemaking would affect epoxy resin manufacturers that produce basic liquid epoxy resin, which is often used to produce a cured resin with desired